K051694

DEC 2 1 2005

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS for ClickZip Needle Retractable Safety Syringe (per 21CFR807.92)

1. SUBMITTER's NAME

Medical Device Manufacturer (Thailand) Ltd.
7/145 Amata City Industrial Estate
Pluakdaeng, Rayong 21140
Thailand

Contact: Ms. Oytip Kunwunlop, Compliance Director
Phone: 66 1 844 7959
Fax: 66 38 956 429

2. DEVICE NAME

Trade Name: ClickZip™ Needle Retractable Safety Syringe
Common Name: Safety Syringe
Classification: II
Classification Name: Piston Syringe with Safety Feature
Classification Code: MEG
Nominal Capacity: 1, 3 and 5 ml.

3. PREDICATE DEVICE

SECUREGARD® Retractable Safety Syringe with 510(K) number K012121.

4. DEVICE DESCRIPTION

The ClickZip™ Needle Retractable Safety Syringe is sterile, single-use, disposable and non-reusable, needle retractable safety syringe, provided with various size of needle. The products are supplied in many sizes i.e. 1, 3 and 5 ml.

5. INTENDED USE

The ClickZip™ Needle Retractable Safety Syringe is to be used for intra-muscular or subcutaneous injection of medications into a patient and is intended to prevent needle stick injuries. It is currently available in 1ml, 3ml and 5ml sizes. ClickZip™ Needle Retractable

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Safety Syringe is not intended to be used for withdrawing blood. In addition, when the syringe user breaks the plunger, reuse of the syringe is prevented.

6. SUBSTANTIAL EQUIVALENCE

Medical Device Manufacturer (Thailand) Ltd. makes a claim of substantial equivalence of the SECUREGARD^{R} Retractable Safety Syringe with 510(K) number K012121 based on similarities in intended use, design, technological and operational characteristics. Both are indicated for injecting fluids into the body and should not be used for blood collection. Both ClickZip^{TM} and SECUREGARD^{R} Retractable Safety Syringe are always supplied with needle attached. Medical Device Manufacturer (Thailand) Ltd. believes that the difference between the ClickZip^{TM} Needle Retractable Safety Syringe and the predicate device are minor and they raise no new issues of safety or effectiveness.

7. PERFORMANCE SUMMARY

ClickZip^{TM} Needle Retractable Safety Syringe has been shown to meet internationally recognized standards for syringe performance i.e. ISO 7864, ISO 7886-1, ISO 10993 series, and ISO 11135. These include physical specification, chemical specification, biocompatibility and sterilization specification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 1 2005

Mr. Oytip Kunwunlop
Compliance Director
Medical Device Manufacturer (Thailand) Limited
7/145 Moo 4
Amata City Industrial Estate
Rayong,
THAILAND 21140

Re: K051694
Trade/Device Name: ClickZip™Needle Retractable Safety Syringe
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: December 2, 2005
Received: December 8, 2005

Dear Mr. Kunwunlop:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Section IV

STATEMENT OF INDICATIONS FOR USE

510K Number (if known): K051694

Device Name: ClickZip™ Needle Retractable Safety Syringe

Indications for Use:

The ClickZip™ Needle Retractable Safety Syringe is to be used for intra-muscular or subcutaneous injection of medications into a patient and is intended to prevent needle stick injuries. It is currently available in 1ml, 3ml and 5ml sizes. ClickZip™ Needle Retractable Safety Syringe is not intended to be used for withdrawing blood. In addition, when the syringe user breaks the plunger, reuse of the syringe is prevented.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use
Per 21 CFR 801.109

Division of General, Restorative, and Neurological Devices

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(Optional Format 1-2-96)